IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
CENTRAL DIVISION AT WORCESTER

UNITED STATES OF AMERICA, Plaintiff, v. DANIEL R. MAROLD, an individual d.b.a. CHILL6, Defendant.	**Civil Case No. 22-cv-11773**

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. Defendant Daniel R. Marold sells "Chill6," a powdered beverage that he claims will cure, treat, mitigate, and prevent a host of diseases, including anxiety disorder, insomnia, alcoholism, and even post-traumatic stress disorder (PTSD). The Defendant's unapproved new drug also contains Phenibut HCl, a substance that is an unsafe food additive under the law. Despite multiple admonishments, the Defendant continues to illegally distribute Chill6 to the public.

2. The United States therefore brings this statutory injunction proceeding under the Federal Food, Drug, and Cosmetic Act (the "Act" or the "FDCA"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin and restrain the Defendant from: (a) violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) nor exempt from approval; and (b) violating 21 U.S.C. § 331(a)

by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), and/or articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).

JURISDICTION AND VENUE

3. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

4. Venue in this District is proper under 28 U.S.C. § 1391(b).

DEFENDANT

5. Defendant Daniel R. Marold is a sole proprietor doing business as "Chill6."

6. Defendant distributes a product known as Chill6 in flavors Orange Mango, Watermelon Jolly, Margarita Lime, Pink Lemonade, and Placiditea. The Chill6 product contains, among other things, N-Acetyl L-Tyrosine, Taurine, Gamma-Aminobutyric Acid, Mucuna Pruriens Extract, L-Theanine, and Phenibut HCl.

7. Defendant has control over the formulation and labeling of Chill6. Defendant is also responsible for the content of his product's website, www.chill6.com. Defendant uses the website to market Chill6 and to receives online orders for the product. A copy of the website is included and marked as Exhibit 1.

8. Defendant conducts business as Chill6 from a residence at 26 Valley Forge Circle, West Boylston, Massachusetts 01583, within the jurisdiction of this Court.

DEFENDANT UNLAWFULLY DISTRIBUTES AN UNAPPROVED NEW DRUG

9. It is a violation of the Act to introduce or deliver for introduction into interstate commerce a "new drug" that is neither approved by FDA nor exempt from approval. 21 U.S.C. §§ 331(d), 355(a). Specifically, a "new drug" may not be introduced or delivered for introduction

into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval. 21 U.S.C. §§ 331(d), 355(a), (b), (j).

Chill6 Is a Drug

10. Under the Act, a product that is intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" is a drug within the meaning of 21 U.S.C. § 321(g)(1)(B).

11. An intended use of a product may be determined from any relevant source, including labeling. *See* 21 C.F.R. § 201.128.

12. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The labeling includes anything that explains the uses of the drug, such as marketing material, regardless of whether it is physically attached to the product itself. *See Kordel v. United States*, 335 U.S. 345, 349–50 (1948).

13. Chill6 is a drug within the meaning of the Act because it is intended for use in the cure, mitigation, treatment, or prevention of disease in man. According to Chill6's labeling, including but not limited to materials on Defendant's website, www.chill6.com, Chill6 is intended to cure, mitigate, treat, and/or prevent at least four diseases: (1) insomnia, (2) alcoholism, (3) post-traumatic stress disorder (PTSD), and (4) anxiety disorder. *See* Ex. 1.

14. Defendant's website contains claims that Chill6 cures, mitigates, treats, and/or prevents insomnia, alcoholism, PTSD, and anxiety disorder, including:

a) "Phenibut has been used safely in Russia for over 50 years, . . . safely treating hundreds of thousands of people for a variety of disorders, including; anxiety, insomnia, mental stress, alcoholism and post-traumatic stress disorder (PTSD). . . . Chill6™ uses the smallest,

effective dose to provide anxiety relief, lowering the risk of any withdrawal when you decide to stop using Chill6™." Ex. 1 at 6; *see also* https://www.chill6.com/ (last visited Sept. 8-9, 2022).

b) "I started getting over the top anxiety, with horrible panic attacks [anxiety disorder]. I've always had anxiety but this was worse . . . . Out of desperation I tried taking the chill6 . . . . I felt the effects that night and the next day." Ex. 1 at 5; *see also* https://www.chill6.com/ (last visited Sept. 8-9, 2022).

c) "Lowering both, your physical and mental anxiety[.] . . . Lowers your mental anxiety: Phenibut . . . has been used all over the world for decades, . . . treating hundreds of thousands of people for a variety of disorders, including; anxiety, insomnia, mental stress, alcoholism and post-traumatic stress disorder (PTSD). . . . Chill6™ uses the smallest, effective dose to provide anxiety relief, lowering the risk of any discomfort when you decide to stop using Chill6™." Ex. 1 at 13; *see also* https://www.chill6.com/products/stress-relief (last visited Sept. 8-9, 2022).

Chill6 Is a New Drug

15. Under the Act, a "new drug" is "[a]ny drug . . . the composition of which is such that" (1) "such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ." or (2) "such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p)(1)–(2).

16. For a product to be "generally recognized as safe and effective" ("GRASE"), within the meaning of 21 U.S.C. § 321(p)(1), three conditions must be satisfied. First, there must be substantial evidence of its effectiveness. The Act defines "substantial evidence" as "evidence

consisting of adequate and well-controlled investigations, including clinical investigations . . . on the basis of which it could fairly and responsibly be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d). Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and thereby subject to peer evaluation, criticism, and review. *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be a consensus among the experts, based on those published investigations, that the product is safe and effective under the conditions prescribed, recommended, or suggested in its labeling. *Id.*

17. FDA conducted comprehensive searches of the publicly-available medical and scientific literature and determined there are no published adequate and well-controlled investigations or any other scientific literature demonstrating that Defendant's Chill6 product is GRASE for any use. Because there are no adequate and well-controlled investigations of the intended use of Defendant's Chill6 product, qualified experts cannot come to a consensus of opinion concerning the effectiveness of the Chill6. Therefore, Defendant's Chill6 product is not GRASE and is a new drug under 21 U.S.C. § 321(p)(1).

Defendant's Chill6 Product Is an Unapproved New Drug

18. After searching its records for NDA, ANDA, and investigational new drug (IND) submissions by Defendant, FDA ascertained that there are no approved NDAs, ANDAs, or INDs in effect for Chill6.

19. Therefore, Defendant's Chill6 product is an unapproved new drug within the meaning of 21 U.S.C. § 355(a).

DEFENDANT UNLAWFULLY DISTRIBUTES A MISBRANDED DRUG

20. The introduction into interstate commerce of any drug that is misbranded is a violation of the Act, 21 U.S.C. § 331(a).

21. Under the Act, a drug is deemed misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it is not exempt from this requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

22. The directions for use on the Chill6 product's label fail to provide, at a minimum, the usual quantity of dose for persons of different ages and the time of administration in relation to time of meals, time of onset of symptoms, or other time considerations. *See* 21 C.F.R. § 201.5(a)–(f).

23. Adequate directions for use, including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures are premised on a body of animal and clinical data derived from extensive, scientifically controlled testing.

24. There is no existing body of scientific data on which adequate directions for use for Defendant's Chill6 product can be based.

25. A prescription drug is "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). Adequate directions for lay use cannot be written for prescription drugs. *See* 21 U.S.C. § 353(b)(1)(A); 21 C.F.R. § 201.5.

26. Chill6 is a prescription drug because it is intended for the curing, mitigating, treating, and/or preventing of diseases, including but not limited to insomnia, alcoholism, PTSD, and anxiety disorder, that require diagnosis and management by a physician. Consequently, there are no adequate directions under which a layman can safely use this drug because it is not safe for use except under the supervision of a physician.

27. Defendant's Chill6 product is not exempt from the requirement for adequate directions for use because it is not the subject of an approved NDA or ANDA. *See* 21 C.F.R. §§ 201.100(c)(2) and 201.115.

28. Therefore, Chill6 is a misbranded drug within the meaning of 21 U.S.C. § 352(f)(1) and does not qualify for an exemption.

DEFENDANT UNLAWFULLY DISTRIBUTES AN ADULTERATED FOOD

29. A product may meet the definitions of both food and drug under the Act. Food is defined in the FDCA as, inter alia, "articles used for food or drink for man or other animals." 21 U.S.C. § 321(f).

30. The Chill6 product label declares the product to be a dietary supplement. A dietary supplement is a food within the meaning of 21 U.S.C. § 321 and is defined to mean, in relevant part, a product "intended to supplement the diet" with one or more "dietary ingredients," that is not represented as a conventional food, and is labeled as a dietary supplement. 21 U.S.C. § 321(ff).

31. Although Chill6 is labeled as a dietary supplement, the Defendant represents Chill6 as a conventional food. *See* 21 U.S.C. § 321(ff)(2)(B). The Chill6 website describes the product as a "vitality drink" and "anti-anxiety drink" and depicts the product alongside an iced beverage in a cup. Ex. 1 at 1. These statements and vignettes contextually imply that the Chill6 product is to be used as a beverage. The Chill6 product label also includes directions to prepare as a drink: "Suggested Usage: . . . Start by stirring 2 scoops (1 serving) of Chill6™ (use Chill 6™ scooper in jar) into 8 oz. of cold water. If necessary, add water to produce your desired flavor and sweetness level."

32. In addition, Chill6's various flavors describe and depict different conventional foods and are marketed based on taste. For example, the name of Chill6's "favorite" flavor, Pink Lemonade, is also the name of a conventional food. Ex. 1 at 1, 8; *see also*

https://www.chill6.com/products /stress-relief?variant=21372437561403 (last visited Sept. 20, 2022). Similarly, the name of another flavor, Margarita Lime, also includes the conventional food term "margarita." Ex. 1 at 8; s*ee also* https://www.chill6.com/products/stress-relief?variant=34634174365856 (last visited Sept. 20, 2022). And the flavor called PlacidiTea is marketed as a "sweet tea." Ex. 1 at 2, 9; s*ee also* https://www.chill6.com/products/stress-relief?variant=39650387722416 (last visited Sept. 20, 2022). Another flavor, Watermelon Jolly, is depicted with two unwrapped hard candies that resemble the popular candy Jolly Rancher®, suggesting that Watermelon Jolly has similar flavors and, like the candy, is intended for conventional food use. Ex. 1 at 10; *see also* https://www.chill6.com/products/stress-relief?variant=33767851163707 (last visited Sept. 20, 2022). Similarly, the Orange Mango flavor is depicted garnished with slices of mango and orange. Ex. 1 at 9; s*ee also* https://www.chill6.com/products/stress-relief?variant=38079628247216 (last visited Sept. 20, 2022).

33. Defendant's various representations about Chill6 convey to the public that Chill6 is a conventional food because, among other things, Defendant calls it a drink, depicts it served as a beverage over ice with a fruit garnish, names several flavors of Chill6 after commonly known beverages, and highlights Chill6's conventional food attributes like taste and hydration, both directly and by using images of candy and fruit to suggest that Chill6 has similar flavors and is also a conventional food. The Defendant himself also directly informed FDA that Chill6 is not a dietary supplement.

34. Whether Chill6 is a dietary supplement within the meaning of 21 U.S.C. § 321(ff) or a conventional food within the meaning of 21 U.S.C. § 321(f), it is a food under the Act. A

dietary supplement is deemed to be a food within the meaning of the Act, except for purposes of the drug definition. 21 U.S.C. § 321(ff). The exceptions under 21 U.S.C. § 350f do not apply.

Chill6 Contains Phenibut HCl, an Unsafe Food Additive

35. Under the Act, a food—whether a conventional food or a dietary supplement—is adulterated if it contains any unsafe food additive. 21 U.S.C. § 342(a)(2)(C)(i).

36. A "food additive" includes, in relevant part, any component substance except (1) a substance covered by a "prior sanction" issued before September 6, 1958; (2) a substance generally recognized as safe ("GRAS") by qualified experts for its intended use in food, either based on common use in food prior to January 1, 1958 or based on data developed through scientific procedures; or (3) a "dietary ingredient" described in 21 U.S.C. § 321(ff) in, or intended for use in, a dietary supplement. *See* 21 U.S.C. § 321(s). Thus, a substance that is not one of the types of dietary ingredients identified in 21 U.S.C. § 321(ff)(1), and does not meet the other exceptions listed in 21 U.S.C. § 321(s), is a "food additive" under the Act, and a substance that is not in, or intended for use in, a "dietary supplement," and does not meet the other exceptions listed in 21 U.S.C. § 321(s), is a "food additive" under the Act.

37. Chill6 contains Phenibut HCl, a synthetic gabapentenoid that is the salt formulation of Phenibut. Phenibut and Phenibut HCl are nootropic drugs and share the same parent compound. Phenibut and Phenibut HCl are used interchangeably in scientific literature. FDA analysis of the Chill6 product confirmed the presence of Phenibut HCl.

38. Phenibut is not currently the subject of a prior sanction issued before September 6, 1958, or a food additive regulation establishing safe conditions of use.

39. FDA conducted comprehensive searches of the generally available literature and has found no evidence that Phenibut was intentionally added to food prior to 1958. The generally

available literature indicates that Phenibut was not synthesized until the 1960s. Therefore, Phenibut does not meet the "common use in food" exception.

40. FDA conducted comprehensive searches of the publicly available medical and scientific literature and determined there is no adequate technical evidence of safety and the general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of Phenibut for use in food. Therefore, Phenibut is not GRAS for use in food. The publicly available literature raises concerns regarding the safety of Phenibut.

41. Phenibut HCl does not meet the other exceptions listed in 21 U.S.C. § 321(s).

42. FDA evaluated published scientific literature and searched food databases and concluded that Phenibut HCl cannot be a dietary ingredient as it does not meet any of the dietary ingredient category descriptions. *See* 21 U.S.C. § 321(ff)(1). FDA advised the public as early as April 29, 2019 that phenibut does not fit any of the dietary ingredient categories. *See* https://www.fda.gov/food/dietary-supplement-products-ingredients/phenibut-dietary-supplements.

43. Therefore, Phenibut is a food additive within the meaning of 21 U.S.C. § 321(s).

44. Under 21 U.S.C. § 348(a), a food additive is deemed unsafe unless it is used in conformity with a regulation prescribing conditions under which it may be safely used, it has been granted an exemption for investigational use under 21 U.S.C. § 348(j), or it is a food contact substance. Phenibut is not a food contact substance, there is no regulation prescribing the conditions under which Phenibut may be safely used, and no exemption for investigational use has been granted under 21 U.S.C. § 348(j). Therefore, Phenibut is unsafe under 21 U.S.C. § 348, and the Chill6 product containing Phenibut HCl is adulterated under 21 U.S.C. § 342(a)(2)(C)(i) because it contains an unsafe food additive.

DEFENDANT DISTRIBUTES CHILL6 IN INTERSTATE COMMERCE

45. "Interstate commerce," under 21 U.S.C. § 321(b)(1), means commerce between any State and any place outside of it.

46. Defendant's website contains an e-commerce page from which customers can and do purchase the product for shipment throughout the country. *See* Ex. 1 at 125-128. Using the website, FDA purchased two 9.03-ounce bottles of Chill6, Pink Lemonade flavor, and requested the product be shipped to Virginia.

47. On or about August 24, 2021, Defendant shipped Chill6 from Massachusetts to Virginia, which constitutes distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1). The shipping package that arrived in Virginia bore a return address of 26 Valley Forge Circle, West Boylston, Massachusetts.

48. Therefore, Defendant violated 21 U.S.C. § 331(d) and 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, unapproved new drugs, misbranded drugs, and/or adulterated food within the meaning of the Act.

FDA WARNED DEFENDANT THAT HIS CONDUCT IS UNLAWFUL

49. Defendant is well aware that his conduct violates the law and that continued violations could lead to regulatory action.

50. On July 20, 2021, FDA issued a Warning Letter based on an internet review of the Chill6 website (www.chill6.com), stating that the claims on the Chill6 website establish that the product is a drug under section 201(g)(1)(B) of the Act because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The Warning Letter explained that Defendant's product is an unapproved new drug, a misbranded drug, and an adulterated food under the Act. The

letter went on to warn Defendant that the failure to correct these violations could lead to regulatory action, including seizure and/or injunction.

51. On July 22, 2021, Defendant responded to the Warning Letter via email. He did not commit to compliance with the law, stating in part:

> Never, ever write me a letter telling me what to do! Are you even serious! This isn't even a dietary supplement and nowhere on the site does it claim that … Never, ever waste tax payer [*sic*] money sending such nonsense or I'll have you removed! … If you ever get tyrannical with me, I'll use my second amendment rights.

52. FDA held a Regulatory Meeting with Defendant on November 9, 2021. Defendant did not agree to any corrective actions during the meeting. Following the meeting, Defendant claimed in an email: "I redid my entire site! . . . I took a lot off! Added Cautions and Warnings in pictures (scroll through pics)." Based on Defendant's email, FDA conducted a limited website review on November 10, 2021. FDA sent Defendant an email on November 10 acknowledging receipt of his November 9 email and stating that the changes made do not address the violations in the July 20, 2021 Warning Letter. As of September 20, 2022, the Chill6 website remained substantially similar to the previous versions of the website.

53. As of October 12, 2022, the Chill6 website lists each of the Chill6 flavors as "Sold Out" with a statement promising a "NEW formula being made..."

54. Unless restrained by order of this Court, Defendant will continue to violate the Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Issue an injunction restraining and enjoining Defendant, and each and all of his directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a)

and the inherent equitable authority of the Court, from doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval; and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), and/or food that is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).

II. Order that FDA be authorized pursuant to this injunction to inspect Defendant's place(s) of business and all records relating to the manufacturing, preparing, processing, packing, receiving, labeling, holding, and distributing of any drug or food to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendant at the rates prevailing at the time the inspections are accomplished; and

III. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

Dated: October 17, 2022

Respectfully submitted:

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